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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,100	08/28/2003	Richard Scott Weston	115.11a	9860
29995 7590 05/02/2008 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614				
EXAMINER ANDERSON, CATHARINE L				
ART UNIT		PAPER NUMBER		
3761				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/652,100

Applicant(s)

WESTON, RICHARD SCOTT

Examiner

Lynne Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 and 53-65 is/are pending in the application.
4a) Of the above claim(s) 32-40 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-31, 53-65 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/S5108)
Paper No(s)/Mail Date 2/29/08
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 1 February 2008 have been fully considered but they are not persuasive.
2. In response to the applicant's argument that Orgill fails to disclose two absorbable matrix layers having different rates of absorption, it is noted that Orgill discloses two absorbable matrix layers 125a and 125b, as shown in figure 8B. Since first matrix layer 125a is initially located closer to the wound site, it will be absorbed at a faster rate than the second matrix layer 125b, which will not be absorbed until after the first matrix layer 125a is absorbed. Therefore, the first matrix layer 125a has a faster rate of absorption than the second matrix layer 125b, and Orgill anticipates the present claims.
3. In response to the applicant's argument that Orgill fails to disclose tube 120 being embedded within the absorbable matrix 105, it is noted that Orgill shows in figure 5 tube 120 embedded within the absorbable matrix 105.
4. In response to applicant's argument that Allen is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Allen teaches the use of a visual temperature indicator in absorbent article, including

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bandages (i.e. wound dressings), as disclosed in paragraph [0014]. Therefore, the teachings of Allen are applicable to the wound dressing of Orgill.

5. In response to the applicant's argument that Zamierowski fails to disclose means for monitoring pressure, it is noted that the invocation of 35 U.S.C. 112, 6th paragraph, in the present claims requires the prior art to disclose the structure disclosed in the present specification and equivalents thereof. The present specification discloses the means for monitoring pressure in the form of hills or bumps on the cover, and further discloses the equivalent structure of bellows in the cover (see claims 10 and 11). Therefore, the bellows disclosed by Zamierowski fulfill the claimed limitations of an equivalent structure to the means for monitoring pressure, and Zamierowski anticipates the present claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-2, 4-5, 24, 26, 29, 53-57, 59, and 63-65 are rejected under 35

U.S.C. 102(e) as being anticipated by Orgill et al. (2003/0108587).

8. Orgill discloses all aspects of the claimed invention with the exception of first and second absorbable layers. Orgill discloses an appliance for administering a reduced

pressure treatment to a wound, as described in paragraph [0012]. The appliance comprises a cover 115 and an absorbable matrix 105, as shown in figure 8A. The cover 115 creates a seal, as disclosed in paragraph [0040]. The matrix 105 is bio-absorbable, as disclosed in paragraph [0034], and comprises a first matrix layer 125a and 125b, as shown in figure 8B. Since first matrix layer 125a is initially located closer to the wound site, it will be absorbed at a faster rate than the second matrix layer 125b, which will not be absorbed until after the first matrix layer 125a is absorbed.

9. With respect to claim 2, the matrix 105 comprises more than one type of absorbent material, as disclosed in paragraph [0034].

10. With respect to claim 4, the cover 115 includes a temperature sensitive material 170, as shown in figure 10A.

11. With respect to claim 5, a segment of tubing 120 is embedded in the matrix 105, as shown in figure 5.

12. With respect to claim 24, a temperature measuring means 170 measures the temperature of the wound, as disclosed in paragraph [0094].

13. With respect to claims 26, 29, and 64, the temperature measuring means 170 comprises a temperature-sensitive material 180 which is located between the cover 115 and wound, as shown in figure 10A, and is therefore integral with the cover.

14. With respect to claim 53, a port 120 supplies reduced pressure within the cover 115, as shown in figure 7A.

15. With respect to claims 54-55, a multisensor 170, as shown in figure 10A, monitors pressure and temperature, as disclosed in paragraphs [0092-0094] and figure 4.
16. With respect to claim 56, a source of suction is provided, as disclosed in paragraph [0034].
17. With respect to claims 57 and 63, a conduit 120 communicates with a source of reduced pressure.
18. With respect to claim 59, the first matrix layer 125a completely covers the bottom surface of the second matrix layer 125b, as shown in figure 8B, and therefore substantially surrounds the second layer.
19. With respect to claim 65, the second matrix layer 125b is located closer to the cover, as shown in figure 8B, and has a lower rate of absorption than the first matrix layer 125a due to its greater distance from the wound site.
20. Claims 6, 8-11, 14, 16-21, and 61-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Zamierowski et al. (2003/0050594).
21. Zamierowski discloses an appliance for treatment of a body comprising a cover 108, as shown in figure 5, and a seal, as described in paragraph [0061]. The cover 108 further comprises a projection in the form of hills or bellows 110a, as shown in figure 5A, and therefore comprises means for monitoring pressure integral with the cover. The cover is capable of compression to provide a visual indication of pressure, as disclosed in paragraph [0059]. The appliance further comprises a packing material 114 and an

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absorbable matrix 106, as shown in figure 5. A conduit 36 is in communication with a source of reduced pressure, as shown in figure 5.

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claims 3 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. (2003/0108587) in view of Lockwood et al. (2002/0065494).

24. Orgill discloses all aspects of the claimed invention with the exception of an adhesive material on the cover. Lockwood teaches the use of an adhesive material on the outer edge of the cover 62 of a wound treatment appliance, as shown in figure 3. The adhesive provides for a secure attachment of the appliance to the skin of the patient. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the cover of Orgill with an adhesive material, as taught by Lockwood, so the cover may be securely attached to a patient.

25. Claims 27-28 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. in view of Allen et al. (2003/0014025).

26. Orgill discloses all aspects of the claimed invention with the exception of a temperature change material that changes color to indicate a change in temperature. Allen teaches the use of a temperature change material that signals a change in the

temperature of a patient by changing color, as disclosed in paragraph [0059]. The temperature change material may be used in a bandage, as disclosed in paragraph [0014]. The temperature change material of Allen allows a user to visually detect a change in temperature of a patient due to the color change. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the temperature sensor of Orgill with a temperature change material that changes color, as taught by Allen, to allow a user to visually detect the change in temperature.

27. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. (2003/0108587) in view of Boynton et al. (7,004,915).

28. Orgill discloses all aspects of the claimed invention with the exception of a data processor, alarm, and display attached to the temperature measuring device. Orgill discloses the desire for a controller to monitor and control the temperature measuring device, as shown in figure 7 and described in paragraphs [0092] and [0099]. Orgill further discloses the importance of sensing a change in the temperature and maintaining the optimum temperature, as disclosed in paragraph [0093].

29. Boynton teaches the use of a data processor having an alarm and display for monitoring a wound treatment apparatus, as shown in figures 4a and 4b. The processor allows for feedback from the sensors to be processed and for the user to monitor and maintain the variables being measured by the sensors. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the apparatus of Orgill with the data processing system taught by Boynton to allow for

feedback from the sensors to be processed and for the user to monitor and maintain the variables being measured by the sensors.

30. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. (2003/0108587) in view of Johnson et al. (7,070,584).

31. Orgill discloses all aspects of the claimed invention with the exception of a third absorbable matrix layer. Johnson teaches wound dressing having three bioabsorbable matrix layers, as disclosed in Claims 8 and 11, to provide the predictable result of reducing the need to change the dressing and apply additional bioabsorbable layers. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the wound dressing of Orgill with a third bioabsorbable matrix layer, as taught by Johnson, to provide the predictable result of reducing the need to change the dressing and apply additional bioabsorbable layers.

32. Claims 7, 12-13, 15, and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamierowski et al. (2003/0050594) in view of Lockwood et al. (2002/0065494).

33. With respect to claims 7 and 15, Zamierowski discloses all aspects of the claimed invention with the exception of an adhesive material on the cover. Lockwood teaches the use of an adhesive material on the outer edge of the cover 62 of a wound treatment appliance, as shown in figure 3. The adhesive provides for a secure attachment of the appliance to the skin of the patient. It would therefore be obvious to

one of ordinary skill in the art at the time of invention to provide the cover of Zamierowski with an adhesive material, as taught by Lockwood, so the cover may be securely attached to a patient.

34. With respect to claims 12-13 and 22-23, Zamierowski discloses all aspects of the claimed invention with the exception of the pressure sensor comprising a different color or an audible sound. Use of color changes and audible alarms are well-known in the art as signaling devices. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the appliance of Zamierowski with a different color or an audible sound, to provide a noticeable signal of a change in pressure.

Conclusion

35. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynne Anderson whose telephone number is (571)272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

cla
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Examiner, Art Unit 3761

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